UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,873	08/28/2003	Amnon Peled	26732	7262

7590 06/06/2006

Martin D. Moynihan
PRTSI, Inc.
P. O. Box 16446
Arlington, VA 22215

EXAMINER	
HISSONG, BRUCE D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,873	PELED ET AL.	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-76* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

A. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 18, 23-31, and 41-49, drawn to family 1 peptidic chemokine modulators and compositions thereof, classified in class 530, subclass 300.

II. Claims 10-17, and 32-40, drawn to family 2 peptidic chemokine modulators and compositions thereof, classified in class 530, subclass 500.

III. Claims 19-22, drawn to peptidic chemokine modulator defined in Table I, classified in class 530, subclass 500.

IV. Claims 50-55, drawn to a method of treating disease using family 1 peptidic chemokine modulators, classified in class 514, subclass 2.

V. Claims 56-58, drawn to a method of treating disease using family 2 peptidic chemokine modulators, classified in class 514, subclass 2.

VI. Claims 59-60 and 65-68, drawn to an antibody that recognizes a peptide of group I, and methods of producing said antibody, classified in class 530, subclass 387.1.

VII. Claims 61-62, 69-72, and 74-76, drawn to an antibody that recognizes a peptide of group II, and methods of producing said antibody, classified in class 530, subclass 387.1.

VIII. Claims 63-64 and 73, drawn to an antibody that recognizes a peptide of group III, and method of producing said antibody, classified in class 530, subclass 371.1.

B. The inventions are distinct, each from the other because of the following reasons:

1. Inventions I-III and VI-VIII are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The polypeptides of groups I-III are distinct due to different amino acid sequence and molecular structure, and thus constitute separate inventions. Similarly, the antibodies of groups VI-VIII represent distinct inventions due to different binding specificities, and thus distinct amino acid sequences and structure.

The polypeptides of groups I-III and the antibodies of groups VI-VIII are patentably distinct for the following reasons: while the inventions of both groups I-III and VI-VIII are polypeptides, in this instance, the polypeptides of groups I-III are single chain molecules that function as chemokine modulators, whereas the polypeptides of groups VI-VIII encompass antibodies, including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the polypeptides of groups I-III and the antibodies of groups VI-VIII are structurally distinct molecules; any relationship between a polypeptide of groups I-III and an antibody of groups VI-VIII is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with a polypeptide.

In this case, the polypeptides of groups I-III are molecules that contain multiple regions to which an antibody can bind, whereas the antibodies of groups VI-VIII are defined in terms of binding specificity to a small structure within a peptide of groups I-III. Thus, immunization with a polypeptide of groups I-III would result in the production of antibodies outside the scope of group VI-VIII. Therefore, the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of groups I-III and groups VI-VIII would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and antibody to the polypeptide require different searches. An amino acid search of the full-length protein is necessary for a determination of

novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of groups VI-VIII. Furthermore, antibodies that bind to an epitope of a polypeptide of groups I-III may be known even if a polypeptide of groups I-III is novel. In addition, the technical literature search for a peptide of groups I-III and the antibodies of groups VI-VIII is not coextensive, e.g. antibodies may be characterized in the technical literature prior to discovery of, or sequencing of, their binding target.

2. Inventions IV and V are independent and distinct inventions, each from the other, because the methods are practiced with materially different process steps for materially different purposes, and each method requires a non-coextensive search because of different starting materials, process steps, and goals. In the instant case, the methods IV and V are practiced with the peptides of groups I and II, respectively, and therefore are practiced with materially different starting materials.

3. Invention I is related to invention IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the peptides of invention I can be used in a materially different process. For example, the peptidic chemokine modulators of invention I can be used in *in vitro* cell assays.

4. Invention IV is unrelated to inventions II-III and VI-VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together.

5. Invention II is related to invention V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the peptides of invention II can be used in a materially

different process. For example, the peptidic chemokine modulators of invention II can be used in *in vitro* cell assays.

6. Invention V is unrelated to inventions I, III, and VI-VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions, the different inventions are not disclosed as capable of use together.

C. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

D. Additionally, groups I-III, are subject to further restriction. It is noted that the claims 5, 14, and 19 are drawn to examination of at least one of a number of structurally distinct and non-overlapping peptide fragments. If Applicants elect groups I, II, or III, a specific peptide/SEQ ID NO must be elected from claim 5, 14, or claim19/Table 1, respectively. In order to be fully responsive, applicant is required to further elect a specific peptide. This is NOT an election of species. The claimed peptide fragments are non-overlapping sequences and are structurally distinct chemical compounds, and are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such peptide is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141. By statute "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant.....to elect that invention to which his claim shall be restricted." 37 CRF 1.142(a). See also 37 CFR 1.141(a). It is noted that search more than one of the claimed patentably distinct peptides represents a serious burden for the office.

E. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

F. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

G. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D., can be reached at (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BDH
Art Unit 1646

ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER